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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.     | CONFIRMATION NO.       |
|---|-------------|------------------------|-------------------------|------------------------|
| 10/520,507  | 10/04/2005  | David Danvers Crossman | 3003-1161               | 5480                   |
| 466   | 7590        | 01/29/2008             |                         |                        |
| YOUNG & THOMPSON<br>745 SOUTH 23RD STREET<br>2ND FLOOR<br>ARLINGTON, VA 22202 |             |                        | EXAMINER<br>PANI, JOHN  |                        |
|   |             |                        | ART UNIT<br>3736        | PAPER NUMBER           |
|   |             |                        | MAIL DATE<br>01/29/2008 | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                                 |  |
|------------------------------|-------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/520,507 | Applicant(s)<br>CROSSMAN ET AL. |  |
|                              | Examiner<br>John Pani         | Art Unit<br>3736                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/7/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

1. Claims 1, 2, 4, 8, and 9 are objected to because of the following informalities:

#### In reference to Claim 1

In lines 4-5 it is suggested to replace both instances of "one or more" with --at least one-- in order to increase clarity. In line 5 it is suggested to replace "members" with --member--. In line 6 it is suggested to replace "features" with --feature--. In line 6 it is suggested to replace "the outer walls" with --outer walls--. In line 7 it is suggested to replace "members" with --member--. In line 7 it is suggested to insert --at least on-- prior to both "locating" and "cooperating". In line 8 it is suggested to replace "features" with --feature--.

#### In reference to Claim 2

In lines 2-3 it is suggested to replace both instances of "or each" with --at least one--.

#### In reference to Claims 4, 8, and 9

It is suggested to replace "sprung-loaded" with --spring-loaded--.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,817,603 to Turner et al. ("Turner").

4. Turner teaches:

In reference to Claim 1

A blood sampling device (see Figs. 1-5B) comprising a needle-carrying lancet (44) located within a housing (36) and having a cap (40) positioned over the needle, the cap extending to project through an opening (42) at one end of the housing and having one locating member (54) fitting into one cooperating feature (42) of the outer walls of the housing, the cap being twistable to release the locating member from the cooperating feature such that the cap can be detached from the housing and from the needle (see col. 6 lines 1-5, by detaching 40 from 36, it is also detached from the needle).

In reference to Claim 4

A blood sampling device according to claim 1 (see above) wherein the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (see Figs. 2-4)

In reference to Claim 5

A blood sampling device according to claim 4 (see above) including a trigger-releasable (54 acts as a trigger to release 44 from 48) latch (60) to hold the lancet within

the housing such that an exposed needle cannot project through said opening until the latch is released by the trigger (see Fig. 2 and 5A-5B).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 3, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in view of US Pat. No. 3,165,220 to Haynes ("Haynes").

In reference to Claim 2

Turner teaches the device of claim 1 (see above) but does not teach that the locating member is a flange and that the cooperating feature is a groove. Turner teaches that the cap is attached to the housing with a frangible seal so that the user knows that the device is unused (see col. 6 lines 1-5). Haynes teaches a tamper-proof container enclosure in which the cap includes flanges (**34**) while the container includes grooves (**18**). The device includes frangible buttons/pins **28** which when broken, indicate that the original seal has been broken (see col. 1 line 60 – col. 2 line 60). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Turner by substituting a tamper-proof enclosure using flanges, grooves, and pins as taught by Haynes, for the heat-sealed frangible cap taught by Turner, because this substitution of one known tamper-proof enclosure for

another would lead to the predictable result of allowing the user to know whether the device was previously used.

In reference to Claim 3

Turner in view of Haynes teaches the device of claim 2 (see above), and Haynes further teaches that there are two flanges fitting into grooves in two opposed sides of the outer walls of the housing (see Figs. 3-5).

In reference to Claims 8 and 9

Turner in view of Haynes teaches the device of claims 2 and 3 (see above) and Turner further teaches that the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (see Figs. 2-4).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 1/24/08

A handwritten signature in black ink, appearing to read "M. H. [unclear]", located in the bottom right corner of the page.